UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,741	12/05/2003	Paul Kudrna	PA047	1700

57346 7590 08/22/2007

HEATHER AKARTSOUNES
520 W. ERIE STREET
SUITE 210
CHICAGO, IL 60610

EXAMINER	
MENDOZA, MICHAEL G	

ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
08/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/728,741	KUDRNA ET AL.	
	Examiner	Art Unit	
	Michael G. Mendoza	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 17-19* is/are rejected.

7)☒ Claim(s) *21 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

*a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant should submit an argument under the heading "Remarks" pointing out disagreements with the examiner's contentions. Applicant must also discuss the references applied against the claims, explaining how the claims avoid the references or distinguish from them.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1-15, 18, and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Freeman, U.S. 2003/0083686. Freeman discloses a tissue penetration device that uses magnetic forces. Figure 5 is a good representation of one of Freeman's embodiments termed "a cylindrical electric lancet driver" (paragraph 0031).

4. With regard to claim 1, Freeman discloses a lancing method of driving an iron core 46 ("member") with magnetic forces produced by the coil pack 52 ("magnetic element"). The "member" 46 is in communication with the lancet 42, and the system is used to pierce a user. (Freeman, paragraph 0138)

With regard to claim 2, the coil patch is also used to "withdraw the driven lancet."

(Id.)

5. With regard to claim 3, a tip of the lancet in Freeman exits the housing 40 to puncture the user. (Id.)

With regard to claim 4, the lancet 42 is withdrawn back into the housing 40 by the magnetic element 52 and member 46. (Id.)

6. With regard to claim 5, driving the lancet 42 involves the member 46 passing through the magnetic element or coil patch 52, as can be seen in figure 5.

With regard to claim 6, the lancet 42 is in communication with the member 46 and is driven by magnetic forces emanating from the coil patch 52. The magnetic forces attract and repel the lancet into and out of the housing 40 for the purpose of piercing a user. (Freeman, paragraph 0138)

7. With regard to claim 7, the lancet is also withdrawn back into the housing 40 by the magnetic forces. (Id.)

8. Applicant's claims 8-1S, 18-19 read on Freeman's embodiment in figures 20-22. With regard to claim 8, the coils 214-217 are considered the "magnetic element" or, in the alternative, the permanent bar magnet 219 may be considered the "magnetic element." Freeman also discloses that one or more of the coils 214-217 can be replaced with permanent magnets (paragraph 0174). Freeman's magnetic member 202 is considered the "member capable of being affected by magnetic forces." Both the magnetic element and member are within a "housing" 180 (or 188 and 191). Also, the device shown in figures 20-21 is to be placed in a larger housing shown in figures 52 or

53. The lancet 183 is in communication with the member 202 and is movable between a withdrawn position and a piercing position by movement of the member 202. The "armed position" is considered to be the position shown in figure 21 where the permanent bar magnet 219 is holding the member 202 in place prior to activation of the coils 214-217. Releasing the member from the armed position is accomplished by activating the coils 214-217, and the magnetic forces created by current running through the coils 214-217 causes the member and lancet to move from a withdrawn position to the piercing position.

9. With regard to claim 9, as mentioned above, the permanent bar magnet 219 effectively holds the member 202 in place, the lancet being in a withdrawn position.

10. With regard to claim 10, adjusting the lancet for selectively controlling the positioning of the piercing position is discussed in paragraph 0194. Freeman discloses either mechanically or electrically adjusting this parameter and others.

11. With regard to claim 11, as can be seen in figure 21, the member 202 passes through the coils 214-217, i.e. one is permitted to pass through the other and the other to pass around the one.

12. With regard to claim 12, the lancet is connected by means of the drive coupler 185 so that movement of the member 202 results in corresponding movement of the lancet. The drive coupler allows replacement of the lancet for future connecting.

13. With regard to claim 13, the magnetic element 219 is oriented and configured so that in the armed position, the magnetic forces of the magnetic element 219 attract the member 202 to the magnetic element 219. The member 202 is released by drawing current through the coils 214-217 and the member can be said to travel "towards" the magnetic element 219 and past the magnetic element 219 by the momentum of the traveling member created by the magnetic pull of the coils. This movement of the member results in the lancet traveling to the piercing position. Also, as discussed above, Freeman discloses the ability to interchange some of the coils 214-217 with permanent magnets (paragraph 0174). These additional permanent magnets can be considered the "magnetic element." If some of the coils were replaced with permanent magnets, the additional permanent magnets in the coil housings 214-217 would also hold the member 202 in a steady state position. Upon triggering the device and allowing current to run through the remaining coils, the member 202 would be attracted to the magnetic field created by the coils and the member would travel "towards" the "magnetic element" (the magnetic element consisting of the permanent bar magnet 219 and the permanent magnets used in place of the coils).

14. With regard to claim 14, the magnetic element 219 is oriented and configured to create a steady-state position that can be said to be between the withdrawn position and the piercing position. "Between" is defined as "In or through the position or interval separating" by The American Heritage® Dictionary of the English Language: Fourth Edition. The steady-state position can be said to be "between" the withdrawn position

and the piercing position. Also, the magnetic forces of the magnetic member 219 hold the member 202 concentric therewith.

15. With regard to claim 15, the same process is described with regard to claim 13, except for the addition of "through the steady state position concentric with the magnet" and "back to the steady state position resulting in the lancet traveling to the piercing position and back to a position within the housing." The process described above with regard to claim 13 applies to the process in claim 15. The member 202 is released from the magnetic pull of the magnetic element 219 by creation of another magnetic pull by the coils, which creates momentum in the member 202. This momentum allows the member 202 to pass through the steady state position which it was in prior to activation of the coils 214-217. After the member moves towards the coils, the current in the coils is reversed, and the member and lancet then travel back to a position within the housing (the housing for the lancet shown in figures 52 or 53).

16. With regard to claim 18, the disposable sampling module 410 in figure 51 is considered the end cap because along with the chamber 430 and socket 432, it houses the lancet 414. This "end cap," or disposable sampling module 410, is releasably connected to the socket 432 for disposal purposes.

17. With regard to claim 19: a switch is defined as "A device used to break or open an electric circuit or to divert current from one conductor to another" by The American Heritage® Dictionary of the English Language: Fourth Edition. In Freeman, a "switch" or sensor activates a driver which opens an electric circuit causing the finger to be lanced.

Pressure is what activates the sensor in the same way that pressure activates a switch. This process is described in Freeman, paragraph 0019.

Remarks

18. With regard to the addition of "permanent" (Freeman, paragraph 0174, lines 1-3)

Allowable Subject Matter

19. Claims 16, 21, and 22 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MM

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER